510(k) Summary [as required by 21 CFR 807.87(h) and 807.92]

Date Prepared [21 CFR 807.92(a)(1)]
September 14, 2004

Submitter's Information [21 CFR 807.92(a)(1)]

Lee Zagar
Miltex, Incorporated
589 Davies Drive
York, PA 17402

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade name is: Miltex Laparoscopic Instruments.

Common name: Monopolar Laparoscopic Instruments, Laparoscopic Grasping Forceps, Laparoscopic Dissecting Forceps, Laparoscopic Scissors, and Laparoscopic Biopsy Punch and Forceps.

Predicate Device [21 CFR 807.92(a)(3)]

- CooperSurgical Laparoscopic Instruments- CooperSurgical Incorporated- K021237.

The subject devices have the same indications for use as the predicate devices, have stainless steel jaws, are both sold non-sterile, and have monopolar electrocautery capability. The main differences are a change in the material for the handle (stainless steel versus carbon fiber).

Description of the Device [21 CFR 807.92(a)(4)]

These devices represent a family of monopolar laparoscopic instruments that consist of:

- Stainless Steel Handle (non-ratcheted)
- Stainless Steel Pull Rod attached to a stainless steel jaw
- Insulation material composed of PPSU (PolyPhenylSulfone)

Various configurations of the jaw (graspers, cutters, dissectors, and punches) exist to meet the needs of the surgical procedure. The instruments have the capability for monopolar electrocautery to allow for the cutting and coagulation of soft tissue.

These reusable instruments are sold non-sterile. The instruments are packaged in a labeled plastic bag.

Intended Use [21 CFR 807.92(a)(5)]

The devices are intended to manipulate tissue, organs, or bowel during laparoscopic surgery. The secondary function is to provide monopolar electrocautery capability to dissect and coagulate tissue.

Technological Characteristics [21 CFR 807.92(a)(6)]

Miltex Incorporated believes that the subject device is substantially equivalent to the predicate device.

Performance Data [21 CFR 807.92(b)(1)]

The patient contact materials are commonly used in medical devices and have a long history of biocompatibility. The stainless steel 420 is complaint with the DIN 17442 standard for Corrosion Resistant Steels for Medical Equipment. The subject devices can withstand 5000V and are compliant with EN 60601-2-18 *Medical electrical equipment- Part 2: Particular requirements for the safety of endoscopic equipment.*

Conclusion [21 CFR 807.92(b)(3)]

We believe that the changes are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 - 2005

Mr. Lee Zagar
Vice President of Quality Assurance
and Regulatory Affairs
Miltex, Inc.
589 Davies Drive
YORK PA 17402

Re: K043013
Trade/Device Name: Miltex Laparoscopic Instruments
Regulation Number: 21 CFR §884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: 85 HET
Dated: January 31, 2005
Received: February 1, 2005

Dear Mr. Zagar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043013

Device Name: Miltex Laparoscopic Instruments

Indications for Use:

The devices are intended to manipulate tissue, organs, or bowel during laparoscopic surgery. The secondary function is to provide monopolar electrocautery capability to dissect and coagulate tissue.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lippman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043013